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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NEW YORK, NY 10020

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/406,575

Applicant(s)

BACHINSKI ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,27-75,87 and 89-147 is/are pending in the application.
- 4a) Of the above claim(s) 25,27-43 and 95-143 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-75,87,89-94 and 144-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Withdrawal of Finality

Upon review of Applicants' remarks filed with the after final amendment and in view of the prior art of record. The Examiner decided to withdraw the finality of the previous Office action and the rejections set forth therein. In particular, the Goldsteen rejections are no longer considered proper because the addition of Rudy Mazzocchi as inventor to the present application, made the inventive entities of Goldsteen and the present application identical.

Election/Restrictions

Claims 25, 27-43, and 95-143 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse by original presentation.

Claim Objections

Claims 46-52 and 65-75 are objected to as having the same scope. In particular, each of claims 46-52 have a scope that is identical to each other. In addition, claims 69-72 have the same scope. Finally, claims 73-75 have identical scopes. If these claims are allowed, Applicant will be required to cancel all but one of the duplicate claims of each set.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-75, 87, 89-94, and 144-147 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

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subject matter which applicant regards as the invention. The present claims scopes are confusing because the preamble sets forth a single "anastomotic connector", yet the bodies of the claims require connection of two blood vessels therewith as if they are adjacent to one another. Applicants' remarks in this regard in the most recent after final amendment did not clarify the claim scope in that they suggested that the two blood vessels are a coronary artery and an aorta. Rather, it may be that Applicants are trying to claim that the connector is adapted to connect a graft to a blood vessel; the graft can be made of a natural material such as a blood vessel.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 44-57, 63-75, 87, 89-94, and 144-147 are rejected under 35 U.S.C. 102(b) as being anticipated by Marin et al (US 5,397,355), or alternatively, under 35 U.S.C. 103(a) as being obvious over Marin et al (US 5,397,355) in view of Venbrux (US 5,443,497) or Trout (US 5,207,695). Marin reads on the claim language where connecting to an opening in a blood vessel is merely a statement of intended use. Since the device of Marin is capable of connecting a graft to a blood vessel, it is also capable of connecting a blood vessel to an opening of another blood vessel to the extent that this claim language can be given weight because the connection need not be at the opening but can be endoluminally located with respect to the opening; see column 1, lines 11-68, the figures, and column 2, line 39 to column 4, line 2.

Alternatively, it is not explicitly clear that the Marin device is capable of forming a connection between an opening in a sidewall and the two blood vessels as claimed. However, Venbrux or Trout teach that it was known to form fluid tight connections between grafts and blood vessels; see the front pages of each patent. Therefore, it is the Examiner's position that it would have been at least obvious to use Marin to attach a blood vessel to an opening and another blood vessel so that the device of Marin could

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be used to bypass a weakened or obstructed portion of the vasculature preventing further complications thereat.

Claims 44, 57, 63-75, 87, 89, 91, 92, and 94 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldsteen et al (US 6,136,007). Goldsteen anticipates the claim language where a different entity is set forth, but the same assignee is present as the present application; see Figures 4 to 6 as well as column 3, lines 40-62 and column 4, line 32 to column 5, line 10.

Claims 44-60, 62-75, 87, 89-94, and 144-147 are rejected under 35 U.S.C. 102(e) as being anticipated by Gifford, III et al (US 5,695,504). Gifford anticipates the claim language where the spikes as claimed are met by the fingers (296) of Gifford; see Figure 25A to 26E and note how the axial contraction results in radial expansion, and see column 69, lines 31-62.

Regarding claim 59, Applicants are directed to column 9, line 49 to column 10, line 6 and column 13, lines 33-54.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44, 45, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmeister et al (US 6,582,461) in view of Marin et al (US 5,397,355) or Gifford, III et al (US 5,695,504). Burmeister discloses the use of bicomposite material

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in expandable devices, but fails to disclose the used of a spike structure to engage tissue at or near an opening as claimed; see the figures and the Detailed Description of the Preferred Embodiments. However, both Marin and Gifford teach that it was known to use spikes or fingers in similar expandable devices to better attach these devices either to a blood vessel, as in Marin, or directly to an anastomotic opening, as in Gifford. Therefore, it is the Examiner's position that it would have been obvious to use spikes or fingers in conjunction with the Burmeister devices for the same reasons that Marin or Gifford use the same.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action unless such applications are stored in image format (i.e. IFW). Generally, those applications filed or amended after July 1, 2003 are image file wrapper (IFW) applications.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (571) 272-4758. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (571) 272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
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